

Countermeasure Injury Compensation Program (CICP)

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Covered diseases:

- Influenza (pandemic, **Not** Seasonal)
- Anthrax, Botulism, Smallpox, Radiation
 - And Benefits include:
 - Unreimbursed medical expenses if applicable
 - Lost wages if applicable
 - Death benefit if applicable
- Covered diseases are added through PREP Act Declarations issued by the Secretary

Why Issue a Declaration under the PREP Act?

- Issued when the Secretary determines a threat to health constitutes a current or future Public Health Emergency with the recommendation for manufacture, development, distribution, and/or use of a countermeasure
- Provides broad liability protection to encourage the manufacture, development, distribution, and/or use of a countermeasure
- Provides compensation to those seriously injured as a result of the countermeasure

Conditions needed for CICP eligibility

- Programmatic conditions met (1 yr filing deadline)
- Countermeasure is covered within a Declaration and it caused a serious adverse event
 - A serious adverse event is life threatening or results in permanent injury or necessitates medical intervention to prevent permanent injury
- Countermeasure is used or a good faith belief exists that it is used
 - within coverage dates specified in the Declaration
 - for the disease or health threat specified in the Declaration
 - for the population & geographic area specified in the Declaration
 - for situations specified in the Declaration.

Focus on Flu: Pandemic

Countermeasures currently covered in CACP

- Influenza A monovalent vaccine (intranasal and injectable) for H1N1, H5N1, H2, H6, H7, H9. **CACP does NOT cover seasonal trivalent vaccine**
- Oseltamivir (Tamiflu), and Zanamivir (Relenza)
- Pandemic influenza diagnostics, personal respiratory protection devices (such as N-95 masks) and respiratory support devices (such as mechanical ventilators)
- <http://edocket.access.gpo.gov/2009/pdf/e9-14948.pdf>
- <http://edocket.access.gpo.gov/2008/pdf/e8-24733.pdf>
- <http://edocket.access.gpo.gov/2008/pdf/e8-30510.pdf>
- <http://edocket.access.gpo.gov/2009/pdf/e9-14412.pdf>

Focus on Flu: Pandemic monovalent influenza vaccine coverage

- Anyone who uses a covered vaccine (including adjuvant) between 6/15/09 and 3/31/13 for monovalent H1N1 or between 12/1/06 and 2/28/10 for monovalent H5N1, H2, H6, H7, H9
- Anyone who uses a covered vaccine as
 - An investigational drug in a clinical trial conducted by the federal government or through a contract, grant, or cooperative agreement with the federal government or
 - In a pandemic period
- Broad coverage as all pandemic vaccine is:
 - Federally purchased
 - And we are currently in a pandemic period

Focus on Flu: Antivirals (Tamiflu and Relenza) and diagnostics and devices (N 95 mask and mechanical ventilator) for Pandemic use

- The Countermeasure is used
 - to combat threatened or actual highly pathogenic human influenza viruses
 - that have developed into a pandemic strain (like pandemic H1N1) or that may be capable of doing so (like avian H5N1) and
- The Countermeasure is administered between 10/10/08 and 12/31/15 for antivirals and 12/17/08 to 12/31/15 for diagnostics and devices

Focus on Flu: Antivirals (Tamiflu and Relenza) and diagnostics and devices (N 95 mask and mechanical ventilator) for Pandemic use

- And Countermeasure coverage includes activities
 - as part of an authorized medical response to a publically declared emergency within its specified dates or
 - as part of research and development for the Federal Government (including any contract, grant or cooperative agreement with the Federal Government) or
 - As part of a human clinical trial conducted by the Federal Government (including through any contract, grant or cooperative agreement with the Federal Government).

Compare and Contrast

CICP

- Administrative
- No legal fees paid
- Decisions regarding causation based on valid, reliable, compelling scientific evidence and made by a physician
- No pain and suffering paid
- One step administrative appeal possible. No judicial appeal
- Covers vaccines, drugs, biologics, devices, etc described in PREP Act declarations

VICP

- Judicial
- Legal fees paid
- Decisions regarding causation based on Court interpretation of “more likely than not standard” and made by a special master or judge
- Pain and suffering paid
- Judicial appeal to higher courts allowed
- Covers vaccines recommended for routine administration to children

Compare and Contrast

CICP

- Can only sue manufacturer or administrator for willful misconduct
- One year filing deadline from date of administration or use
- No sequela or surgical requirement (although injury must be serious)
- Covers monovalent pandemic influenza vaccine but not seasonal trivalent vaccine
- Prove injury through
 - Tables or Actual causation

VICP

- Can elect to sue if reject judgment or if exit Program after a prescribed time
- 3 year filing deadline from first manifestation of injury
- 6 months of sequela or surgical intervention or death required (no requirement of serious injury per se)
- Covers seasonal trivalent influenza vaccine but not monovalent pandemic vaccine
- Prove injury through
 - Table or Actual causation

CICP Information

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<http://www.hrsa.gov/countermeasurescomp>